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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,226	11/19/2003	Ji-Young Kim	39894-00601	6919
29880	7590	05/13/2010	EXAMINER	
FOX ROTHSCHILD LLP PRINCETON PIKE CORPORATE CENTER 997 LENOX DRIVE BLDG. #3 LAWRENCEVILLE, NJ 08648				ROBERTS, LEZAH
ART UNIT		PAPER NUMBER		
1612				
			NOTIFICATION DATE	DELIVERY MODE
			05/13/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/717,226	KIM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 February 2010.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 158-164, 166-202, 205-207, 215 and 216 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 158-164, 166-202, 205-207, 215 and 216 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>08 Feb 2010</u>	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

Applicants' arguments, filed February 8, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Priority**

Applicant's amendments to the claims have overcome the previous rejection because the claims are amended such that they have priority to the earliest filing date of March 17, 2000.

#### **Claim Rejections - 35 USC § 103 -Obviousness (New Rejections)**

1) Claims 187, 188, 196, 197, 198, 199-202 and 205-207 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biss et al. (US 5,177,113) in view of Gallopo et al. (US 2001/0002252, already of record).

Biss et al. disclose compositions comprising hydrogen peroxide ( $H_2O_2$ ) and polyvinyl pyrrolidone (PVP) foam. Stabilized peroxide compositions are used as antiseptics and bleaching material. The compositions include PVP with K values of 15 to 90. These have water content of less than 5% and may also be dried to reduce moisture content (col. 2, lines 37-45). Once the  $H_2O_2$  is mixed with PVP, it is dried (col. 2, lines 50-58). Other embodiments include mixing with hydroxyalkyl celluloses, such as hydroxyethyl cellulose; and compounds such as propylene and ethylene glycols as gelling agents (col. 3, lines 16-25). The reference differs from the instant claims insofar as it does not disclose the compositions comprise tripolyphosphate or a polyphosphate.

Gallopo et al. has previously been discussed in detail in the Office Action mailed February 6, 2009 and differ from the instant claims insofar as it does not disclose the compositions are dry.

Biss et al. disclose the PVP- $H_2O_2$  compositions may be used to deliver whitening agents. Generally, it is *prima facie* obvious to combine two components, such as two whitening agents hydrogen peroxide and sodium tripolyphosphate, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Thus it would have been obvious to one of ordinary skill in the art to have delivered polyphosphates or added a polyphosphate to the compositions of Biss et al.

motivated by the desire to deliver an agent suitable for whitening in a vehicle suitable for delivering whitening agents.

The compositions of the combined teachings may comprise an adhesive polymer such as hydroxyethyl cellulose, as disclosed by the instant specification. Thus it is reasonable to conclude that when the compositions of the combined references have a mixture of hydroxyethyl cellulose and PVP, they will have similar adhesive function as those of the instant claims.

2) Claims 158, 159, 166-173, 181-186 and 195 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biss et al. (US 5,177,113) in view of Gallopo et al. (US 2001/0002252, already of record) as discussed above in further view of Tapolsky et al. (US 6,159,498).

Biss et al. and Gallopo et al. are discussed above and differ from the instant claims insofar as they do not disclose hydroxypropyl methyl cellulose as the gelling agent used in the compositions of Biss et al.

Tapolsky et al. has previously been discussed in detail in the Office Action mailed May 3, 2006. The reference discloses the adhesive layer may comprise at least one film-forming water-soluble polymer, usually a cellulose derivative and at least one pharmacologically acceptable polymer known for its bioadhesive capabilities. The film forming polymer used includes hydroxyethyl cellulose and hydroxypropyl methylcellulose (col. 5, lines 44-47). The bioadhesive polymer of the adhesive layer

includes polyvinylpyrrolidone (PVP) (col. 5, lines 61-63). These bioadhesive polymers are preferred because they have good and instantaneous mucoadhesive properties in a dry, film state, which meets the limitation "wherein the patch has adhesive strength" and "as an adhesive polymer".

The reference differs from the instant claims insofar as it does not disclose using peroxide or sodium tripolyphosphate in the compositions.

It is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant disclosure. See *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958); see also *In re Scott*, 323 F.2d 1016, 139 USPQ 297. Hydroxyethyl cellulose and hydroxypropyl methyl cellulose have been disclosed as being equivalent in Tapolsky et al. It would have been obvious to one of ordinary skill in the art to have used a hydroxypropyl methyl cellulose in place of hydroxyethyl cellulose and then in combination of PVP in the compositions of the combined teachings of Biss et al. and Gallopo et al. motivated by the desire to make a whitening composition that has good adhesion to the oral cavity when in a dry state as disclosed by Tapolsky et al.

3) Claims 187-194, 196-202, 205-207, 215 and 216 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (JP 10-17448, already of record) in view of Gallopo et al. (US 2001/0002252, already of record).

Suzuki et al. disclose devices for removing stains comprising two layers (see Abstract). The first layer is an adhesive layer comprising whitening agents such as

hydrogen peroxide; water soluble polymers such as polyvinyl pyrrolidone and hydroxyl ethyl cellulose; and plasticizers such as glycerin and propylene glycol (paragraph 0010 and Examples). The second layer is a support layer (paragraph 0006), encompassing a backing layer. The compositions are freeze dried and become adhesive when wet (paragraph 0011).

The reference differs from the instant claims insofar as it does not disclose the compositions comprise tripolyphosphate or a polyphosphate, nor does it disclose an example comprising PVP, hydrogen peroxide and hydroxyethyl cellulose.

Gallopo et al. has previously been discussed in detail in the Office Action mailed February 6, 2009 and differ from the instant claims insofar as it does not disclose the compositions are dry.

Generally, it is *prima facie* obvious to combine two components, such as two whitening agents hydrogen peroxide and sodium tripolyphosphate; and two polymers for the adhesive layer polyvinyl pyrrolidone and hydroxyethyl cellulose, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Thus it would have been obvious to one of ordinary skill in the art to have combined tripolyphosphate, hydrogen peroxide, PVP and hydroxyethyl cellulose in the adhesive composition of the Suzuki et al. motivated by the desire to make a third composition suitable for the same purpose.

The compositions of the combined teachings comprise an adhesive polymer such as polyvinyl pyrrolidone and hydroxyethyl cellulose, as disclosed by the instant specification. Thus it is reasonable to conclude that the composition of the combined teachings will have a similar adhesive function as those compositions of the instant claims.

4) Claims 158-164, 166-186 and 195 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (JP 10-17448, already of record) in view of Gallopo et al. (US 2001/0002252, already of record) as discussed above in regard to claims 187-194, 196-202, 205-207, 215 and 216, in further view of Tapolsky et al. (US 6,159,498).

Suzuki et al. and Gallopo et al. are discussed above and differ from the instant claims insofar as they do not disclose hydroxypropyl methyl cellulose.

Tapolsky et al. has previously been discussed in detail in the Office Action mailed May 3, 2006. The reference discloses the adhesive layer may comprise at least one film-forming water-soluble polymer, usually a cellulose derivative and at least one pharmacologically acceptable polymer known for its bioadhesive capabilities. The film forming polymer used includes hydroxyethyl cellulose and hydroxypropyl methylcellulose (col. 5, lines 44-47). The bioadhesive polymer of the adhesive layer includes polyvinyl pyrrolidone (PVP) (col. 5, lines 61-63). These bioadhesive polymers are preferred because they have good and instantaneous mucoadhesive properties in a

dry, film state, which meets the limitation “wherein the patch has adhesive strength” and “as an adhesive polymer”.

The reference differs from the instant claims insofar as it does not teach using peroxide or sodium tripolyphosphate in the compositions.

Hydroxyethyl cellulose and hydroxypropyl methyl cellulose have been disclosed as being equivalent in Tapolsky et al. It would have been obvious to one of ordinary skill in the art to have used a hydroxypropyl methyl cellulose in place of hydroxyethyl cellulose and then in combination with PVP in the compositions of the combined teachings of Suzuki et al. and Gallopo et al. motivated by the desire to make a whitening composition that has good adhesion to the oral cavity when in a dry state as disclosed by Tapolsky et al. and supported by cited precedent (See In re Ruff cited above).

### **Obvious-Type Double Patenting**

Claims 158-164, 166-202, 205-207, 215 and 216 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-30 of copending Application No. 11/414,435 in view of Tapolsky (US 6,159,498).

Applicant requests rejection be held in abeyance until allowable subject matter has been indicated. Since this has not occurred, the rejection is maintained.

Claims 158-164, 166-202, 205-207, 215 and 216 are rejected.

Claims 158-164, and 166-172 are objected.

No claims allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612